

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: PHARMACEUTICAL INDUSTRY	)	MDL NO. 1456
AVERAGE WHOLESALE PRICE	)	
LITIGATION	)	CIVIL ACTION: 01-CV-12257-PBS
	)	
	)	Judge Patti B. Saris
THIS DOCUMENT RELATES TO	)	
<i>U.S. ex rel. Ven-A-Care of the Florida Keys,</i>	)	Magistrate Judge Marianne B. Bowler
<i>Inc. v. Abbott Laboratories, Inc.,</i>	)	
No. 06-CV-11337-PBS	)	

**ABBOTT LABORATORIES, INC.'S MEMORANDUM IN  
SUPPORT OF ITS MOTION FOR A PRESERVATION ORDER  
AND AFFIDAVIT REGARDING SPOILIATION ISSUES**

Abbott respectfully moves this Court for an order prohibiting the Government from destroying evidence critical to Abbott's defenses and requiring the Government to explain its prior actions that have resulted in widespread spoliation.

The Government alleges that it paid "tens of millions" of false claims (Ex. A at 2) based on the mistaken belief that the term "average wholesale price" ("AWP") describes the price at which a pharmaceutical firm sells a drug at retail, while published AWP's did not meet this definition. As the Court is well aware, one of Abbott's defenses in this case is that the Government knew that, in the pharmaceutical industry, published AWP's do not reflect a drug's average retail price. With this knowledge, Government officials intentionally created Medicare and Medicaid reimbursement systems that paid providers more than the cost of drugs administered or dispensed to beneficiaries. This differential payment accomplished important policy goals, including ensuring access to care for Medicare and Medicaid beneficiaries.

Abbott has sought evidence of government knowledge and decision-making to further its defenses. At a minimum, such evidence demonstrates a lack of falsity, inasmuch as the Government understood precisely what Abbott's published prices represented. The evidence

also defeats the Government's claim of justifiable reliance. This Court has repeatedly recognized the importance of this evidence.

In violation of its legal obligations, however, the Government has destroyed much of the evidence that would permit Abbott to establish its defenses. As described more fully below, the federal government first circulated a document retention memorandum in January 2007, in apparent response to an Abbott deposition notice regarding document preservation efforts. No document preservation efforts were taken when this case was first filed in 1995, nor when Abbott described its government knowledge defenses in a 2000 white paper submitted to the DOJ, with a subsequent request that the Government preserve documents related to that white paper. The Government likewise took no electronic document preservation steps in 2003, when defendants in MDL 1456 served a subpoena from this Court on the Centers for Medicare and Medicaid Services ("CMS"). In the intervening 12 years, while this action was pending, critical evidence was lost, including the emails of every single departing CMS employee, save one.

Through its motion for a preservation order and affidavit, Abbott seeks to halt any further such destruction, to determine precisely what evidence the Government has destroyed, and to learn what steps might be available to cure past spoliation.

**I. THE GOVERNMENT HAS DESTROYED IMPORTANT AND RELEVANT EVIDENCE.**

The United States' track record with respect to document retention in this matter is shocking. From the time this suit was initiated in 1995, and to the present day, administrators and employees of CMS and other government agencies have used e-mail communications that captured their contemporaneous thoughts about AWP and other issues of relevance to Abbott's defense. Marianne Bowen, the Government's Rule 30(b)(6) witness regarding the preservation of electronic records, testified that she could have preserved all of these e-mails, as early as 1995, had she only been asked to do so. (Ex. B at 259:16-261:5) However, no document

retention or litigation hold memo was issued in connection with this case until *January 2007*.

(Ex. C at 77:1-13.) As such, CMS “did not take any steps to preserve” the electronic documents of 27 of the 28 former individuals identified by the Government, in response to Abbott’s second interrogatory, as having knowledge of drug reimbursement policy, and the records were destroyed once each employee’s tenure ended. (Ex. B at 175:10-177:9, 235:20-236:21.) In other words, despite the Government’s unquestionable “duty to preserve [relevant] evidence,” *Townsend v. Am. Insulated Panel Co., Inc.*, 174 F.R.D. 1, 5 (D. Mass. 1997), the Government repeatedly destroyed the e-mails of nearly every ex-employee with knowledge of the issues in this case, even after it learned of Abbott’s potential “government knowledge” defense. This was improper. *See, e.g., AmeriPride Svcs., Inc. v. Valley Indus. Serv., Inc.*, No. CIV-S-00-113, 2006 WL 2308442, at \*4 (E.D. Cal. Aug. 9, 2006) (“[A]s soon as a potential claim is identified, a litigant is under a duty to preserve evidence which it knows or reasonably should know is relevant to the action.”).

The Court can understand the scope of this problem by examining one specific example of the extensive spoliation in which the Government has engaged. Bruce Vladeck was the administrator for HCFA/CMS between May 1993 and September 1997. Dr. Vladeck describes himself as an “extensive e-mailer” and believes that he “could very well have” used e-mail to communicate with others about drug reimbursement issues. (Ex. D at 102:5-10, 309:20-310:8.) There is strong reason to believe that Dr. Vladeck’s emails would have contained information regarding the government knowledge defense. After filing this case in 1995, relator Ven-A-Care gave a presentation to CMS and DOJ regarding its allegations, and even sent letters directly to Dr. Vladeck regarding the claims in this case. (*Id.* at 263:11-271:2.) While Dr. Vladeck was administrator, CMS proposed legislation to remove AWP from the drug reimbursement formula

and replace it with actual acquisition cost. (*Id.* at 367:19-371:5.) Government investigators issued numerous reports regarding AWP, and *Barron's* published an article describing the allegations of this case. (*See, e.g., id.* at 511:20-512:16, 517:20-522:7, 533:19-539:13, 557:16-559:21.) All contemporaneous CMS e-mails regarding these topics, however, have been destroyed, including specifically Dr. Vladeck's communications. (Ex. B at 175:10-177:9, 235:20-236:21.)

The Government's spoliation did not end with Dr. Vladeck's tenure. Rather, the Government continued to destroy evidence even after it received unambiguous notice that government knowledge would be at issue in this False Claims Act litigation. In March 2000, responding to the DOJ's threat to unseal the Ven-A-Care *qui tam*, several pharmaceutical companies submitted a white paper to the Department explicitly setting forth their government knowledge defense; Abbott, though not an original signatory, joined in the white paper on September 1, 2000.<sup>1</sup> (Exs. E, F.) This submission included several specific statements regarding AWP made by government officials, including then-Administrator of HCFA Nancy-Ann DeParle. (Ex. E at 11-17.) The submission sought to demonstrate government awareness that AWP was a "sticker price." (*See generally id.*) Further, in an August 2000 letter to the DOJ discussing the white paper, an attorney for one of the pharmaceutical companies expressly asked the DOJ to "take appropriate and immediate steps to insure that your client agencies (including at a minimum HHS [and] HCFA. . .) maintain all documents that may be relevant to the subject matter of this litigation or reasonably calculated to lead to the discovery of admissible evidence." (Ex. G at 2.) Despite this explicit request for document retention, as well as the unambiguous

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<sup>1</sup> The United States referenced the white paper and attached a copy of the white paper's cover letter in its opposition to Dey's Motion to Dismiss. *See* United States Memorandum in Opposition to Dey Defendants' Motion to Dismiss the United States Complaint at 3-4 & Att. 5, *United States ex rel. Ven-A-Care of the Florida Keys Inc. v. Dey, Inc.*, No. 01-12257 (D. Mass. filed Feb. 2, 2007).

notice of the defendants' likely government knowledge defense (including the specific evidence that would be relevant to that defense), the Government continued to destroy emails and other documents of CMS officials, particularly those who left government service. (Ex. B at 175:10-177:9, 235:20-236:21.)

The Government's destruction of evidence continued through 2003 and 2004, even after CMS was served with third-party subpoenas issued by this Court in MDL 1456. (Ex. H.) These subpoenas made it clear that documents relating to the Government's awareness and decision-making in the area of drug reimbursement were relevant to active litigation. (*See generally id.*) (The Government, of course, knew that the evidence was also relevant to sealed litigation in which it was a party.) Here again, a specific example will provide vivid context to the Government's improper actions.

Thomas Scully was the Administrator of CMS from 2001 through 2003. (Ex. I at 49:10-50:13.) Scully used email extensively, even sending a daily message to all 4,000 CMS employees describing what he was doing that day. (*See id.* at 79:9-80:10.) Scully testified that prescription drug reform and "fixing AWP" were his top priorities when he joined CMS. (*Id.* at 376:17-377:9, 381:13-16.) Scully left government service on January 4, 2004—over two months after the first subpoena was served in MDL 1456. (*Compare id.* at 50:12-13 with Ex. H.) In connection with an unrelated matter, Scully's personal counsel requested that CMS produce the former Administrator's emails in March or April of 2004, only three to four months after he left CMS. CMS responded that the emails no longer existed. (Ex. I at 74:20-80:4.) In fact, Scully's laptop computer was sitting, unsearched, in the office of Marianne Bowen, who had the hard drive erased and put the computer back in service in late 2004. (Ex. B at 100:6-105:12.) No documents from that computer were produced in response to the MDL 1456 subpoenas.

Only after this case was unsealed, and Abbott subpoenaed the records custodian and the head of CMS's IT division, did the Government put a litigation hold into place. Pursuant to that hold, the e-mails and electronic documents of exactly *one* ex-employee, Tom Gustafson, have been preserved. (*Id.* at 272:4-273:14.) E-mails of four current CMS employees identified as persons with knowledge of AWP issues appear to be available currently. (*Id.* at 223:7-225:11.)<sup>2</sup> Even as to these four, CMS has made no efforts to secure their electronic data for use in this litigation, and the employees remain free to delete emails as they choose. (*Id.* at 270:10-272:3.)

The harm to Abbott from this document destruction is self-evident given the Government's twelve-year delay in unsealing. Deposition testimony, however, has reinforced the scope of that harm. The CMS personnel whose records the Government destroyed consistently claim to have diminished memories of their knowledge and activities while in office. For instance, Tom Scully testified that his "ability to remember what happened 17 years ago [when he first addressed AWP issues] is somewhat diminished" and that his recollection of AWP policy could have been given "more accurately" had he been asked questions in 1995. (Ex. I at 497:15-498:19.) Bruce Vladeck testified that if he wanted to "try to reconstruct" various details related to drug reimbursement during a particular time period, looking at his old e-mails "would certainly be a very useful spur to the memory." (Ex. D at 310:2-311:3.) Finally, Charles Booth, who had been Director of HCFA's Office of Payment Policy, could not specifically testify about his knowledge and understanding of AWP because, in his words, "I'm 70 years old. I have not dealt with these issues for at least 13 years." (Ex. J at 154:6-157:21.) Indeed, every Government witness to date who has been asked to testify regarding critical events during the relevant time period (1991-2001) has claimed some degree of memory loss. Contemporaneous

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<sup>2</sup> The deposition transcripts excerpts here refer to five current employees; the fifth is Mr. Gustafson, who was later described as an ex-employee for whom documents were retained. (Ex. B at 272:4-273:14.)

communications would have gone a long way toward filling those gaps, but the Government's wanton destruction of documents has defeated Abbott's efforts to obtain such evidence.

**II. A PRESERVATION ORDER IS APPROPRIATE GIVEN THE FACTS AND CIRCUMSTANCES OF THIS CASE.**

Federal courts, when faced with a party's destruction of relevant evidence, have the authority to issue preservation orders which are "not unduly burdensome and [are] necessary, at a minimum, to preserve" a party's rights. *Williams v. Mass. Mut. Life Ins. Co.*, 226 F.R.D. 144, 147 (D. Mass. 2005). For instance, in *Pueblo of Laguna v. United States*, 60 Fed. Cl. 133, 134, 138 (2004), the Court held that preservation should be ordered where there was a "significant risk that relevant evidence will be lost or destroyed," such as where the "opposing party has lost or destroyed evidence in the past or has inadequate retention procedures in place." Likewise, in *Capricorn Power Co., Inc. v. Siemens Westinghouse Power Corp.*, 220 F.R.D. 429 (W.D. Pa. 2004), the court held that preservation orders would be judged by balancing three considerations:

- 1) the level of concern the court has for the continuing existence and maintenance of the integrity of the evidence in question in the absence of an order directing preservation of the evidence;
- 2) any irreparable harm likely to result to the party seeking the preservation of evidence absent an order directing preservation; and
- 3) the capability of an individual, entity, or party to maintain the evidence sought to be preserved, not only as to the evidence's original form, condition or contents, but also the physical, spatial and financial burdens created by ordering evidence preservation.

*Id.* at 433-34 (paragraph breaks added). Thus, where a "significant past, present or future threat to the continuing integrity or existence of the evidence" existed—such as a "a party. . . intentionally damaging or destroying the evidence"—and such destruction prejudiced the party seeking the order, a preservation order would be granted, particularly where the "evidence is stored upon a computer. . . hard drive" or is otherwise easily maintained. *Id.* at 434-36.

In light of the Government's unjustified destruction of documentary evidence, and the resulting prejudice to Abbott, a preservation order is necessary and justifiable for three reasons.

*First*, the Government has engaged in a pattern of spoliation, destroying evidence despite knowing that such evidence would be of critical importance to Abbott. The Government destroyed this evidence even as it was engaged in one-sided discovery against Abbott in an effort to establish its own case. The Court can have no confidence that the Government will now take appropriate efforts to preserve evidence relevant to Abbott's defense. A court order is the only way to ensure proper preservation.

*Second*, Abbott will be harmed without a preservation order, as there is no reasonable substitute for contemporaneous records of the Government's knowledge regarding AWP. Any case that is 12 years old, and which includes allegations stretching back over 20 years, would raise questions as to the adequacy of witness memory. This Court itself has recognized the danger caused by long delays in unsealing. (*See* Ex. K at 48:21-49:3 ("I've actually had this debate with some members of my local U.S. Attorney's office: What about witness memories? People forget... [and defendants] bear the brunt of it[.]" ).) Abbott has confirmed that, in fact, Government witnesses are unable to provide specific testimony as to their knowledge and actions during the relevant time frame. The only remedy is for the Court to order the Government to immediately preserve all documentary evidence relevant to this case.

*Third*, the Government will not be burdened if it is ordered to live up to its obligations. Whatever burden the Government would bear, moreover, does not justify destruction of evidence. Given the vast financial resources of the United States (and the fact that much of the remaining evidence may be in storage *now*), it is unlikely that the Government could provide any plausible reason that would make a preservation order unduly burdensome here. Indeed, Julie



Boughn, a 30(b)(1) witness with knowledge of the information technology systems at CMS, testified that it would be easy to retain and store e-mails, and that CMS does so often for OIG investigations. (Ex. L at 223:14-229:5.) Of course, private parties dealing with the United States “have a public obligation to provide evidence, and. . . this obligation persists no matter how financially burdensome it may be.” *Hurtado v. United States*, 410 U.S. 578, 589 (1973). The same should be true for the United States when it is the plaintiff in civil litigation.

### **III. THE COURT SHOULD ORDER THE GOVERNMENT TO ACCOUNT FOR THE DESTROYED EVIDENCE AND DESCRIBE RECOVERY EFFORTS.**

In addition to its preservation order, the Court should order the Government to explain, in an affidavit, exactly what evidence was destroyed, when it was destroyed, whether it is recoverable by any means, and if so, the recovery efforts undertaken thus far. That affidavit should likewise explain what efforts were taken to avoid spoliation of evidence and attach unredacted copies of all document retention memoranda. *See Chavannes v. Protective Life Ins. Co.*, 232 F.R.D. 698, 702 (S.D. Fla. 2006) (ordering, in advance of spoliation decision, party to provide affidavits stating, *inter alia*, “whether any of the [allegedly spoliated evidence] have ever existed and. . . whether those items exist today,” and for that evidence which did exist, “the steps, if any, taken by Plaintiff to preserve the [evidence]. . . [and] the steps taken by Plaintiff to locate the [evidence]”); *United Med. Supply Co. v. United States*, 77 Fed. Cl. 257, 263 (2007) (noting Court’s order that Government “file a memorandum explaining the official document retention, preservation, and destruction policies in effect at each [government facility] from 1996 onwards”); *Webb v. United States*, 840 F. Supp. 1484, 1508 (D. Utah 1994) (noting it had “ordered the Government to submit a memorandum explaining the chain of custody regarding [an allegedly spoliated] file, and why it had not been provided to the Plaintiffs earlier”). Such an order is unquestionably proper under this Court’s inherent authority to protect the integrity of the

judicial process. *See Chambers v. NASCO, Inc.*, 501 U.S. 32, 45-46 (1991); *Jimenez-Sanchez v. Caribbean Restaurants, LLC*, 483 F. Supp. 2d 140, 143 (D.P.R. 2007) (noting broad range of “court’s inherent power to manage its own affairs” in response to spoliation).

Such an order is necessary here in order to assess the full extent of the spoliation and the ability of the Government to ameliorate it. Abbott has already discovered that certain evidence might yet be available, but it is also clear that the Government knows more, and could possibly do more, regarding the spoliation that has already occurred. For instance, Marianne Bowen, who admittedly took no steps to preserve the central file of electronic documents relevant to this case, testified that the e-mail records could have been preserved on individual hard drives, diskettes, CDs, or in paper format. (Ex. B at 236:4-9.) Likewise, Vickie Robey, who is responsible for CMS document preservation and retention, testified that no litigation hold was *ever* instituted for documents in archives or those sent to the Federal Records Center, and that individual employees are responsible for collecting and retaining files that may be relevant to this case. (Ex. C at 138:19-147:11.) Nevertheless, although she has records of which documents are in storage, have been recalled from storage, or have been destroyed, she has not produced those records or indices to Abbott. (*Id.*) Government memoranda which purport to detail CMS efforts at collecting and preserving documents, have largely been redacted as “privileged,” as has the 2007 document retention/litigation hold memorandum, even though it was not drafted by an attorney. (*Id.* at 68:3-69:9, 77:6-85:19.) Unredacted versions of such documents could lead Abbott to alternate sources for the spoliated evidence, and would help to explain what steps the Government took to avoid evidence destruction.

Finally, the Court should require the Government to designate a 30(b)(6) witness to give deposition testimony about the topics addressed in the Government’s affidavit. Such an order,

coupled with the preservation order, will allow Abbott and this Court to gain a comprehensive understanding of the spoliation landscape, including whether the spoliation may be remedied, or whether sanctions may be appropriate. If the Court requires that the affidavit be filed in 30 days, and the witness produced within 45 days, a status hearing can be scheduled shortly thereafter.

### CONCLUSION

The Court should order the Government to preserve evidence relevant to this litigation, and order it to provide an affidavit regarding the spoliation, and the possibilities for remediation, as described above.

Dated: September 13, 2007

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I, David S. Torborg, an attorney, hereby certify that I caused a true and correct copy of the foregoing ABBOTT LABORATORIES, INC.'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR A PRESERVATION ORDER AND AFFIDAVIT REGARDING SPOLIATION ISSUES to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 13th day of September, 2007.

/s/ David S. Torborg  
David S. Torborg